UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE: LEVAQUIN PRODUCTS LIABILITY LITIGATION,	MDL No. 08-1943 (JRT)
This Document Relates to:	
CALVIN CHRISTENSEN, EDWARD KARKOSKA, JERRY CULLINS, and WILFRED DELUDE, Plaintiffs, v. JOHNSON & JOHNSON; ORTHO-MCNEIL PHARMACEUTICAL, INC.; JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, LLC; and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; Defendants.	Civil No. 07-3960 (JRT/AJB) **MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENTAS TO PLAINTIFF KARKOSKA**

Ronald S. Goldser, **ZIMMERMAN REED, P.L.L.P.**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402, for plaintiff Edward Karkoska.

John Dames, **DRINKER BIDDLE & REATH LLP**, 191 North Wacker Drive, Suite 3700, Chicago, IL 60606-1698, and Tracy J. Van Steenburgh, **NILAN JOHNSON LEWIS PA**, 400 One Financial Plaza, 120 South Sixth Street, Minneapolis, MN 55402, for defendants.

Edward Karkoska brought suit against Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., and Johnson & Johnson Pharmaceutical Research & Development,

LLC (collectively, "defendants"), after he suffered injuries to his left Achilles tendon. He alleges that the prescription antibiotic Levaquin, which defendants designed, formulated, and marketed, caused those injuries. The case is now before the Court on defendants' motion for summary judgment. (Docket No. 726.) Defendants argue that Minnesota's learned intermediary doctrine precludes Karkoska from establishing proximate causation as a matter of law. For the reasons stated below, the Court denies the motion.

BACKGROUND[1]

Levaquin is the brand name for Levofloxacin, a broad-spectrum anti-infective drug. (*Christensen v. Johnson & Johnson*, No. 07-3960, Am. Compl. ¶ 18, Docket No. 32.) It is part of a broader class of anti-infective drugs, including Ciprofloxacin, called fluoroquinolones, or simply quinolones. (*Id.* ¶ 19.)

A. Karkoska's Medical History

Edward Karkoska is currently 81 years old and lives in Eveleth, Minnesota. Prior to his tendon injury in January 2004, he had been prescribed Levaquin on three occasions: March 6, 2003, October 16, 2003, and November 4, 2003. (Apr. 19, 2010 Zizic Report, Goldser Aff. Ex. 1, Docket No. 1304.)

On March 6, 2003, a physician prescribed Levaquin to treat Karkoska's bronchitis. On April 14, 2003, Karkoska complained of pain in his anterior outer right leg, between

[1] The Court views the facts and evidence in the record in the light most favorable to Karkoska, the non-moving party. *Riley v. Lance*, 518 F.3d 996, 999 (8th Cir. 2008).

his knee and his ankle. (Butner Dep. at 139-40, Van Steenburgh Aff. Ex. A, Docket No. 729.[2])

On September 5, 2003, Karkoska had surgery to replace his right hip. (Apr. 19, 2010 Zizic Report, Goldser Aff. Ex. 1, Docket No. 1304.) On October 16, 2003, a physician prescribed Levaquin to treat Karkoska for chronic inflammation of the wall of his gallbladder. (*Id.*) The following day, Karkoska had a laparoscopic gallbladder procedure. (*Id.*)

On November 4, 2003, when Karkoska was 75 years old, Dr. Butner saw Karkoska for the first time. (*See id.* at 5.) Karkoska complained of congestion and a cough that had developed in the period after his gallbladder operation. Dr. Butner concluded that Karkoska had bronchitis "that probably is somewhat related to his general anesthetic" from the gallbladder procedure. (*Id.*) Dr. Butner observed that "sulfa is giving him some relief, but we probably need to move on to a more potent, broad-spectrum antibiotic." (*Id.*) Noting that Karkoska also had "significant issues regarding his prostate," Dr. Butner prescribed a ten-day course of therapy with Levaquin, expressing the opinion that the drug "should help with chronic prostatitis." (*Id.*)

At the time Dr. Butner prescribed Levaquin, the package insert included the following warning about tendon issues:

> Ruptures of the shoulder, hand or Achilles tendons that required surgical repair or resulted in prolonged disability had been reported in patients

[2] Dr. Butner's deposition appears in two places in the record. (Van Steenburgh Aff. Ex. A, Docket No. 729; Goldser Aff. Ex. A, Docket No. 757.) The Court hereinafter omits the affidavit and docket information when citing Dr. Butner's deposition.

> receiving Quinolones including Levofloxacin. Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly. Levofloxacin should be discontinued if the patient experiences pain, inflammation or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture can occur during or after therapy with Quinolones including Levofloxacin.

(Butner Dep. at 82-83.) Dr. Butner was aware of this specific warning at the time he prescribed Levaquin to Karkoska. (*Id.* at 83.)

In early January 2004, Karkoska stubbed his toe and heard a pop from his left Achilles tendon. An orthopedist subsequently diagnosed Karkoska with an acute rupture of his left Achilles tendon. (Apr. 19, 2010 Zizic Report, Goldser Aff. Ex. 1, Docket No. 1304.) On January 15, 2004, the orthopedist performed a percutaneous repair of the tendon. (*Id.*)

On June 30, 2004, Karkoska was prescribed Levaquin prior to a transrectal ultrasound with needle biopsy of his prostate. The Levaquin was prescribed "to cover the biopsies." (*Id.*)

On October 26, 2005, Karkoska had a right total knee replacement. In October 2006, he had a left total knee arthroplasty. (*Id.*)

B. Dr. Butner's Deposition Testimony

Dr. Butner is board certified in family medicine. (Butner Dep. at 14.) He is also a theoretical physicist with an interest in particles called "leptons" and "lepton wave model[ing]." (*Id.* at 10-11.)

The learned intermediary doctrine, which forms the basis for defendants' motion for summary judgment, involves an examination of whether the prescribing physician was independently informed of the relevant risks, and whether the prescribing physician would have taken the same course of action even if the defendants had provided additional warnings. *Cornfeldt v. Tongen*, 262 N.W.2d 684, 698 (Minn. 1977); *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970). If a defendant properly establishes the facts necessary to support the learned intermediary defense, a patient will be unable to show that the defendant's failure to warn the prescribing physician is a proximate cause of the patient's injury. *Mulder*, 181 N.W.2d at 885. This doctrine therefore requires the Court to conduct a careful examination of the prescribing physician's experience, knowledge, and state of mind when making the decision to prescribe the particular drug at issue. *See, e.g.*, *Cornfeldt*, 262 N.W.2d at 698. The Court therefore sets forth in detail Dr. Butner's deposition testimony as it relates to this doctrine.

1. How Dr. Butner Assesses Drugs

Dr. Butner testified about how he processes information he receives from pharmaceutical companies about new drugs. He testified that when he receives information from a drug representative about a new product, he tends to "ask a lot of questions trying to define what this product is, what it's designed for." (Butner Dep. at 38.) Then he does independent "research for [his] own purposes," and "tr[ies] to come

up with the actual molecule shape, size, because I have that orientation towards this . . . lepton waving, because it's an interest." (*Id.*)

Dr. Butner testified that his initial research about a new drug generally starts with "either a product information printing that I got either from a drug rep or from a magazine article or some other source, perhaps a lecture . . . at some conference." (*Id.* at 40-41.) Then he looks at the references cited in those sources, either from the drug reps or on the internet. (*Id.* at 41.) Then, after Dr. Butner "ha[s] digested the material as best [he] could and then ha[s] a chance to . . . kind of combine this with [his] other interests," he determines what he thought the drug was, how the drug should work, what the risk factors were, and he "make[s] a niche for it. This is where I think this product would be helpful." (*Id.* at 41-42.)

2. Dr. Butner's Familiarity with Fluoroquinolones

Dr. Butner was aware that fluoroquinolones "like Ciprofloxacin work[] to disrupt an enzyme that has to do with genetic function and . . . the way the gene causes certain proteins to be manufactured." (*Id.* at 39.) Based on his research about Ciprofloxacin, he understood that quinolones could disrupt cartilage growth "because of the way it works, it makes the cartilage or tendons become stiffer and become less pliable and less stretchable." (*Id.* at 39-40.)

Dr. Butner was aware that older age was a risk factor for tendonopathies, and that "[c]ertainly the Quinolones" have had "the most publicity and are the most recognized" for the risk for tendon disorders. (*Id.* at 51.)

Dr. Butner testified that he "was very familiar with Cipro," and understood when Levaquin came on the market that Levaquin was "a newer form of that, so [he] tried to make certain [he] understood how that works[.]" (*Id.* at 40.) He did not "have a specific recollection" of how he had first become familiar with Levaquin. (*Id.* at 37.) He remembered a "conversation with the rep that came in to tell me about it." (*Id.*) Dr. Butner asked the rep "if it was the same mechanism. He said yes." (*Id.*) He then asked the drug rep whether Levaquin had "molecular moieties that make it . . . better? Make it longer acting, since it's a daily dose instead of a BID dose like Ciprofloxacin was? And we had that discussion." (*Id.*)

With respect to Levaquin, Dr. Butner specifically remembered doing his "standard research into the product when it came out." (*Id.* at 80.) He remembered speaking to his "peers in doctors' lounges about antibiotic effects, medicine effects." (*Id.*) He did not recall speaking with people at medical meetings about Levaquin. (*Id.*)

Dr. Butner testified that he had compared Levaquin to Ofloxacin, both with respect to efficacy and with respect to the potential effects the two drugs could have on tendons. (*Id.* at 94.) He testified that he had not seen any studies comparing Levaquin with Ciprofloxacin with regard to tendonopathies. (*Id.* at 95.) He had no recollection of Johnson & Johnson sales reps telling him that studies indicated that Levaquin was twice as "tendon toxic" as Ciprofloxacin. (*Id.* at 95-96.) He was also not aware that "European agencies similar to the FDA were looking at Levaquin and were considering putting in a warning that Levaquin was . . . twice as tendon toxic as Cipro[floxacin]." (*Id.* at 117.)

Karkoska's counsel asked Dr. Butner about his awareness of the differences among the fluoroquinolones with respect to tendon toxicity:

> Q: **Were you aware that in 2001 there were concerns about** Levaquin – reports of **tendon ruptures being more common with Levaquin than with the other Fluoroquinolones?**
>
> [Objection]
>
> A: **I wasn't aware.** I understood there was a general concern of the class in general. **I was not aware of the distinction between the individual members of that class.** [3]
>
> Q: Is that distinction important to you or not, or would it would have been your prescribing practice to know that Levaquin was found to be more tendon toxic than Cipro?
>
> [Objection]
>
> A: As you, I guess, are attempting to lead me to previously with your questions when you described 10, 20, whatever number of more times more toxic, of course, **when I look at any medication, I look at its relative risk.** . . . Then I play off against that how much effectiveness do I get for the alleviation of a symptom or disease and what is my best estimate given all the different factors, as I am aware of them, with regards to each individual patient, where can I get the best and biggest and safest and cheapest bang for the buck, again, emphasizing safety and all the other things that I just mentioned. So, sure, if something had become aware – **if I had become aware of a circumstance where** this medicine, this **Levaquin**, or some other medicine **was having huge issues, I would consider it.**

(*Id.* at 117-18 (emphases added).)

[3] Later in the deposition, Dr. Butner testified that he was aware that as of July 26, 2001, Johnson & Johnson had information indicating that the reporting rate for tendon disorders was higher for Levaquin than for any other fluoroquinolone. (Butner Dep. at 125-26.) In considering defendants' motion for summary judgment, however, the Court must view Dr. Butner's testimony in the light most favorable to Karkoska. For purposes of this motion, the Court therefore disregards this later testimony indicating that Dr. Butner was aware of the tendonopathy distinctions among the fluoroquinolones.

Dr. Butner testified that Levaquin was particularly effective as a broad-spectrum antibiotic. (*Id.* at 48.) In his view, there was a danger that doctors might prescribe Levaquin almost automatically. (*Id.*) He testified that he "tried really hard to practice with discipline, and I said no, I'm going to think this through. Every patient needs my full attention, and I will choose for each patient what I think is best." (*Id.*)

3. Dr. Butner's Decision to Prescribe Levaquin to Karkoska

Dr. Butner testified that he generally considered the following sources of information in deciding whether to use a particular drug: medical literature, medical meetings or conferences where the drug was discussed, his own internet research, his own experience with the drug, package inserts, and the Physician's Desk Reference. (*Id.* at 79-81.)

After reviewing Karkoska's medical file prior to the deposition, Dr. Butner testified that he examined Karkoska for the first time on November 4, 2003. (*Id.* at 17.) Dr. Butner was "just stepping in . . . as a pinch hitter" for Karkoska's attending physician, who was not available. (*Id.* at 45.) At the time of the examination, Dr. Butner reviewed Karkoska's medical records and "did see at least one of [the previous] Levaquin events" in Karkoska's medical history. (*Id.* at 20.) He noted that Karkoska was taking sulfa at the time, but sulfa was "not very effective . . . for respiratory infection" such as bronchitis. (*Id.* at 33-34.) Dr. Butner concluded that Karkoska needed a more potent broad-spectrum antibiotic. (*Id.* at 36.)

Dr. Butner testified that he considered a variety of factors in deciding to prescribe Levaquin:

> Q: What, in your opinion, then – what benefits did Levaquin give? When would you turn to Levaquin versus the other antibiotics you've mentioned?
>
> A: Well, in this – again, I'm doing this trying to put myself back into a mindset that I'm sure I was in when I saw this patient. So, I've got this gentleman who has, in my opinion at that point, evidence of a respiratory infection. He has history of prostate infection, which maybe he's still having issues with. He's on an antibiotic already that may be irritating his stomach. That's a common side effect of the sulfamethoxazoles. He feels uneasy. Well, he's sick. Is he horribly sick? In my judgment, no. But is he sick? Yes. Does his situation require attention? Well, he's a little older. He's come through a procedure. **He's still in the postop period**. He had a previous history of . . . smoking . . . earlier in his years. So, he probably has some **compromised airway structures**. I had already reviewed the chart and had seen the previous labs and had seen that he had adequate creatinine clearances. So, he was not someone who had compromised renal state. So, I said okay, how am I going to manage this.
>
> It has been my experience that **when I follow a sulfa with a cephalosporin that I sometimes will get diarrhea.** So, if I did that and I had this gentlem[a]n who already isn't too pleased with his situation and I give him another symptom complex, he's really going to be unpleased.
>
> Q: And potentially made sicker than he already was; correct?
>
> A: Yes.
>
> [Objection]
>
> A: I'm just trying to decide **what's the best tool for the situation**. And so, when I went through that process, you know, I made that decision – obviously, it's here in the record – that I picked this medicine.
>
> Q: Now, let's go on with the record that you said the patient does have issues with his degenerative arthritis, particularly areas that have tenderness like his right hip where he has a total hip replacement. So, again, part of his history was he had had issues with his hips and arthritic hips?

A: And since – that's right. . . . You say okay, this guy does have some issues with his joint. And as we've already said earlier in this conversation, you know, this medicine does have specific impact on cartilage and joints, and it's black box warned against – for children who still have growth plates. **This guy, obviously, had issues with his joints. So, I'm recognizing that there is a risk here.** There is an element of concern. But **when I played the risk versus benefit, I made the decision that the benefit was greater.**

Q: And in fact, you —

A: Excuse me. I had also reviewed and had seen **he'd used the medicine before.** By quick review, I saw just at least once. You may have come up with it twice, but I saw it once. **He tolerated it the first time okay. That was somewhat reassuring.**

(*Id.* at 43-46 (emphases added).)

Dr. Butner testified that he had not been aware that Karkoska had had any previous tendon issues. (*Id.* at 49.) He testified that he "was totally unaware" that subsequent to a previous prescription of Levaquin, Karkoska had been seen by an orthopedist complaining of pain from his knee to his ankle. (*Id.* at 119.) He testified that he had "no idea" whether such a complaint was consistent with tendonopathy, but that if he "had been given that history, . . . it would have been part of [his] consideration." (*Id.* at 119-20.) Karkoska's attorney inquired as to whether that history would have affected his decision to prescribe Levaquin:

Q: **Would that have changed your prescription** at that point in time if you would have had that information that he had pain from his knee to his ankle after being prescribed Levaquin?

A: I guess on the straight face of your question, I would simply say, **I don't know.** I would have to be back in that situation at that point.

(*Id.* at 120 (emphases added).)

4. Dr. Butner's Responses to Hypothetical Questions About Prescribing Levaquin to Karkoska

Karkoska's counsel posed several questions to Dr. Butner regarding whether information about Levaquin's tendon toxicity would have affected his decision to prescribe Levaquin to Karkoska. Dr. Butner testified that even if he had known in 2003 about studies indicating that Levaquin was twice as toxic as Ciprofloxacin, such knowledge would not have potentially affected the prescription that he gave Karkoska. (*Id.* at 96.) He also testified that even if he had known that Levaquin was reported to be ten times as tendon toxic as **non**-Fluoroquinolones, such knowledge would not have changed what he prescribed. (*Id.* at 111.) Dr. Butner explained:

> The situation that I was in at that point was that **I was very concerned about this gentleman's respiratory status**, and I made a decision trying to use a certain type of medication to effectively help him with his respiratory status. I mentioned in my notes maybe give him some relief also with his prostatitis. As I recall, after reviewing this note, I was, apparently at that point, aware of his previous hip replacement. He already had an issue concerning his hip. I made note that he had some tenderness in the area. So, **I wanted to be as clear as – and I wanted to be as effective as I could be in preventing any type of systemic spread of infection. So, my focus was fix the infection and do it in the most efficacious effective way possible, and yes, the risk factors were all there on the table, and I was evaluating them as best I felt I could.**

(*Id.* at 111-12 (emphases added).)

Dr. Butner testified that even though he ultimately would have prescribed Levaquin, information about Levaquin's relative tendon toxicity likely would have prompted him to take some additional steps in assessing Karkoska:

> And my answer, I guess – again, I'm not trying to be difficult either. If I had then the knowledge that I have now, **I probably would have done several things different.** First, I would have demanded, as best I could, that he get a vitamin D level. I would have found out more about this individual's basic collagen maintenance system. I did not have that knowledge then. From what you seem to have implied, if I had looked

> back with the grace of a retroscope right now – retrospectroscope, I would have made more efforts to find out what exactly his steroid situation was. I would have tried harder to ferret out whether he had had pain from the previous use of the Quinolone, which I don't have any – the note that is here, I don't have – that wasn't a part of my – I wasn't aware of that when I prescribed this. So, sure, I made the best decision I thought that I could. Am I sticking by my guns? You bet. **I did the best I could with what I had at the time.**

(*Id.* at 121-22 (emphases added).)

C. Karkoska's Deposition Testimony and Declaration

Karkoska testified that he was unaware that Dr. Butner had prescribed him Levaquin until he picked up his prescription. (Karkoska Dep. at 25, Van Steenburgh Aff. Ex. B, Docket No. 729.) He testified that he "didn't know what [he] was getting," other than that he "was getting a medication to fix [him] up." (*Id.* at 26.) In a subsequent declaration, Karkoska stated that if he had "been warned of the risk of tendon injury associated with Levaquin by either the patient information leaflet or Dr. Butner, [he] would have taken care to prevent [his] injury from occurring" and he "would have raised" his previous use of Levaquin and subsequent tendon pain with Dr. Butner. (Karkoska Decl. ¶¶ 4-6, Docket No. 766.)

D. Procedural Background

On September 12, 2007, Karkoska filed suit against defendants in this Court. (*Christensen v. Johnson & Johnson*, No. 07-3960, Compl., Docket No. 1.) The Amended Complaint sets forth eight causes of action: strict liability (design defect), negligence, breach of implied warranties, breach of express warranty, fraud, violation of Minnesota's

False Advertising Act, violation of Minnesota's Consumer Fraud Act, and violation of Minnesota's Unlawful and Deceptive Trade Practices Acts. (*Christensen v. Johnson & Johnson*, No. 07-3960, Am. Compl., Docket No. 32.) On June 13, 2008, the United States Judicial Panel on Multidistrict Litigation issued a transfer order to centralize multiple Levaquin-related cases in the District of Minnesota for coordinated or consolidated pretrial proceedings. (Docket No. 1.) On November 24, 2009, defendants moved for summary judgment as to Karkoska. (Docket No. 726.) In addition to filing a memorandum in opposition to the motion, Karkoska's counsel filed an affidavit pursuant to Federal Rule of Civil Procedure 56(f). (Docket No. 1305.) Karkoska's counsel also filed a motion to strike certain portions of defendant's reply brief. (Docket No. 1433.)

ANALYSIS

I. STANDARD OF REVIEW

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that can be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

II. THE LEARNED INTERMEDIARY DOCTRINE

The learned intermediary doctrine pertains to the first two causes of action: strict liability and negligence. The parties agree that Minnesota law governs both claims, and that both causes of action sound in failure to warn.

A. The Learned Intermediary Doctrine Under Minnesota Law

The Minnesota Supreme Court first recognized the learned intermediary doctrine in *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882 (Minn. 1970), a case involving circumstances quite different from the facts presented here. In *Mulder*, the Minnesota Supreme Court held that the doctrine applies if the prescribing doctor intentionally disregards the manufacturer's warnings. *Id.* at 885. The prescribing physician testified that he was familiar with the manufacturer's recommended dosage and "chose not to be governed by it." *Id.* After presenting the case in chief, plaintiff's counsel informed the court that plaintiff's sole theory of liability was whether the doctor was fully aware of the facts which were the subject of the warning. *Id.* The Minnesota Supreme Court affirmed the district court's directed verdict in favor of the defendant, holding that "where the only issue is failure to communicate a warning, the manufacturer is not liable if the doctor was fully aware of the facts which were the subject of the warning." *Id.* The court explained that "[f]ailure (of the doctor) to follow an unchallenged method of use prescribed by the manufacturer constitutes a break in causation which exonerates the manufacturer from any liability." *Id.* (internal quotation marks omitted). In response to a petition for

clarification of the opinion submitted by the Minnesota State Medical Association as amicus curiae, the court stated:

> Where a drug manufacturer recommends to the medical profession (1) the conditions under which its drug should be prescribed; (2) the disorders it is designed to relieve; (3) the precautionary measures which should be observed; and (4) warns of the dangers which are inherent in its use, a doctor's deviation from such recommendations is prima facie evidence of negligence if there is competent medical testimony that his patient's injury or death resulted from the doctor's failure to adhere to the recommendations.

Id. at 887 (per curiam).

In *Cornfeldt v. Tongen*, the Minnesota Supreme Court extended the doctrine to facts similar to those presented in this case, holding that the doctrine applies if the doctor's conduct would have been the same even if the manufacturer had included the warning that plaintiff suggests. 262 N.W.2d 684, 698 (Minn. 1977). Plaintiff argued that the manufacturer's "stuffer sheet" about the drug that the defendant prescribed for plaintiff's surgery was inadequate. *Id.* Citing *Mulder*, the court concluded that at the time of the surgery the prescribing doctor had been aware of the basis for plaintiff's proposed additional warning, "but discounted [it] from his own knowledge and experience." *Id.* The court held that "the claimed deficiency in the warning was not a cause of [plaintiff's] injuries" because the prescribing doctor "made his decision in [plaintiff's] case on the basis of the facts that would have come to his attention had the 'stuffer sheet' read as plaintiff alleged it should have." *Id.*

In *Bruzer v. Danek Medical, Inc.*, the District of Minnesota concluded that a plaintiff must identify some omitted information that would have convinced the

prescribing physician to alter the recommended course of treatment in order to establish causation for failure to warn under Minnesota's learned intermediary doctrine. No. 3-95-971, 1999 WL 613329, at *6 (D. Minn. Mar. 8, 1999). In *Bruzer*, the physician testified that he would have made the same recommendation regardless of the existence or content of any warnings provided by the defendants. *Id.* Summary judgment in defendant's favor was appropriate because "[p]laintiffs have not identified any piece of information that would have convinced him to alter his recommended course of treatment[.]" *Id.*

B. The Learned Intermediary Doctrine as Applied to Karkoska's Strict Liability and Negligence Claims

Defendants argue that there are three independent means of invoking the learned intermediary doctrine as a defense to causation in this case. First, they argue that there is no factual dispute that defendants warned Dr. Butner of the risks of potential tendon rupture associated with Levaquin, and therefore defendants discharged their duty to warn regarding those risks. Second, they argue that Dr. Butner was independently aware of the information underlying the warnings that Karkoska alleges defendants failed to provide. Third, they argue that Dr. Butner's testimony shows that additional information about tendon toxicity would not have altered his decision to prescribe Levaquin to Karkoska. The Court addresses each theory in turn.

1. There Is a Genuine Issue of Fact Regarding the Adequacy of Defendants' Warning.

There is no factual dispute that defendants warned Dr. Butner of the specific risks of potential tendon rupture. Defendants argue that because Dr. Butner testified that he

received information warning of those risks, "Defendants sufficiently discharged their duty to warn regarding the risks of the tendon injury." (Mem. in Supp. at 11, Docket No. 728.) The Court finds, however, that there is a genuine issue of fact regarding the **adequacy** of defendants' warning.

Under Minnesota's learned intermediary doctrine, "a prescription drug manufacturer fulfills its duty to warn by adequately warning the physician . . . of a drug's potential risk." *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1305 (D. Minn. 1988). The crux of Karkoska's claim is that the warning was inadequate. The Court recognizes that there may be factual circumstances in which a warning is adequate as a matter of law, such as where a plaintiff fails to identify "any piece of information that would have convinced any [physician] to alter the recommended course of treatment with regard to" the plaintiff. *In re Orthopedic Bone Screw Litig.*, No. 3-96-1095, 1999 WL 628688, at *15 (D. Minn. Mar. 8, 1999). As a general matter, however, "[i]n a products liability action based on failure to warn, ... [i]f a legal duty to warn is found, the factual issues of the adequacy of the warning, breach of the duty, and causation are . . . considered by the factfinder." *Johnson v. Zimmer, Inc.*, No. 02-1328, 2004 WL 742038, at *9 (D. Minn. Mar. 31, 2004).

The Court finds that there are two factual disputes regarding the adequacy of defendants' warning. First, there is a factual dispute regarding whether any piece of information would have convinced Dr. Butner not to prescribe Levaquin. Although Dr. Butner knew of the general tendon risks posed by fluoroquinolones, he testified that he "was not aware of the distinction between the individual members of that class."

(Butner Dep. at 117.) Moreover, Dr. Butner's testimony suggests that defendants never presented him with definitive information regarding Levaquin's actual tendon toxicity. Dr. Butner testified, "We'll try to quantify it. Was it 2 times, 10 times, 20 times, was it 50 times more toxic to tendons? What do the studies indicate? I need an answer." (Butner Dep. at 124-25.) At the time of Dr. Butner's deposition, Dr. Butner had not seen those studies and did not know the level of tendon toxicity relative to alternative treatments. Therefore, Dr. Butner's testimony does not establish that defendant's warning was adequate as a matter of law.

Second, there is a factual dispute regarding whether any piece of information would have convinced Dr. Butner to alter his assessment of and course of treatment for Karkoska, even if he ultimately would have prescribed Levaquin. Dr. Butner's testimony shows that additional information about Levaquin's relative tendon toxicity would have prompted him to take some additional steps in assessing Karkoska. (*Id.* at 121-22.) Therefore, even though there is no factual dispute that defendants warned Dr. Butner about the specific risks of tendon rupture, there is a genuine issue of material fact regarding the adequacy of defendant's warning.

2. There Is a Genuine Issue of Fact Regarding Whether Dr. Butner Was Aware of the Relevant Risk Information.

Defendants argue that there is no factual dispute that Dr. Butner was aware of the tendon toxicity risks associated with Levaquin and that his awareness was based on his own experience and research. (Mem. in Supp. at 11, Docket No. 728.) This argument is similar to the learned intermediary theory articulated in *Cornfeldt*, where the plaintiff

argued that the manufacturer should have included a more specific warning. Karkoska argues that Dr. Butner's "testimony did not establish that his knowledge regarding the risks of tendonopathy associated with Levaquin encompassed all of those matters that Plaintiff alleges a full and adequate warning should have included." (Mem. in Opp'n at 13, Docket No. 1303.)

The Court finds that there is a genuine issue of fact regarding whether Dr. Butner was aware of the relevant risk information. In particular, Dr. Butner testified that he "was not aware of the distinction [in tendon toxicity] between individual members of [the Fluorquinolone] class." (Butner Dep. at 117.) He testified that he had not seen studies comparing Levaquin with Ciprofloxacin with regard to tendonopathies. (*Id.* at 95.) He also testified that in assessing a new drug, he "dig[s] out the references" and conducts his own examination of the available studies. (*Id.* at 40-42.) Only after "digest[ing] the material" does he reach a conclusion about the drug, its function, and the risk factors. (*Id.* at 41-42.) Based on this testimony, a reasonable trier of fact could conclude that Dr. Butner's independent assessment of Levaquin's risk was not informed by knowledge of the relative risk of Levaquin and Ciprofloxacin. This testimony creates a genuine issue of fact regarding the extent of Dr. Butner's awareness of the relevant risk information, and whether an additional warning "would have merely informed [Dr. Butner] of risks of which he was already aware." *See McCormick v. Custom Pools, Inc.*, 376 N.W.2d 471, 476 (Minn. Ct. App. 1985); *cf. Cornfeldt*, 262 N.W.2d at 698.

3. There Is a Genuine Issue of Fact Regarding Whether Dr. Butner Would Have Altered Karkoska's Course of Treatment.

Defendants argue that "Dr. Butner's decision to prescribe Levaquin® to Mr. Karkoska would not have changed irrespective of additional warnings provided[.]" (Mem. in Supp. at 13, Docket No. 728.) The proper inquiry, however, is not only whether Dr. Butner would have prescribed Levaquin, but also whether he would have otherwise altered the course of treatment if he had received a more thorough warning. *See DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 225 (8th Cir. 1983); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 923 (8th Cir. 1970). Dr. Butner testified that if he had known that Levaquin had greater tendon toxicity than other fluoroquinolones, he "probably would have done several things different." (Butner Dep. at 121.) Dr. Butner explained that he would have conducted vitamin D testing, he would have learned more about Karkoska's "basic collagen maintenance system," and he would have investigated Karkoska's "steroid situation." (*Id.* at 121-22.) Such inquiries may have resulted in a different course of treatment, or may have prompted Karkoska to raise the issue of his previous tendon pain with Dr. Butner. (Karkoska Decl. ¶¶ 5-6, Docket No. 766.) Viewing this testimony in the light most favorable to Karkoska, the Court finds that there is a genuine issue of fact regarding whether additional warnings would have prompted Dr. Butner to conduct a more thorough evaluation of Karkoska's risk factors or otherwise to alter the course of treatment for Karkoska's bronchitis.[4]

[4] Karkoska also argues that Dr. Butner's responses to hypothetical questions about what he would have done if he had received adequate warnings are inadmissible opinions offered by a

(Footnote continued on next page.)

The Court notes two additional problems with defendants' argument. First, after reviewing Dr. Butner's deposition transcript, the Court finds that Dr. Butner's testimony regarding what he would have done if he had received a more complete warning of the risks of tendon toxicity presents an issue of credibility that is within the province of the trier of fact. *See Jenson v. Eveleth Taconite Co.*, 130 F.3d 1287, 1299 (8th Cir. 1997). Dr. Butner expressed uncertainty about Levaquin's actual risks for tendon toxicity relative to other drugs and uncertainty about "[w]hat . . . the studies indicate[.]" (Butner Dep. at 124-25.) When asked whether additional information about Levaquin's tendon toxicity "could . . . have changed [his] prescribing Levaquin to" Karkoska, he replied, "I still **would have gone on with my knowledge at that point**. As best I can ethically and morally reconstruct the situation, I would have picked the same medicine." (*Id.* at 123-24 (emphasis added).) It is unclear from this testimony whether Dr. Butner's "knowledge at that point" includes knowledge about "the distinction between the individual members of [the fluoroquinolone] class" with respect to tendon toxicity. (*Id.* at 117.) At one point in the deposition he testified that he had not been aware of this distinction, but later in the deposition he testified that he had been aware of it. (*Id.* at 125.) At summary judgment, the Court must assume that Dr. Butner was not aware of the distinction. But the Court

---

(Footnote continued.)

fact witness. (Mem. in Opp'n at 16-20, Docket No. 1303.) This argument is unavailing. Rule 701 of the Federal Rules of Evidence allows a non-expert witness to testify "in the form of opinions or inferences" so long as those opinions or inferences "are . . . rationally based on the perception of the witness," helpful to "the determination of a fact in issue," and not based on specialized knowledge within the scope of Rule 702. Fed. R. Evid. 701. The Court finds that, based on the record presently before the Court, Dr. Butner's testimony in response to the hypothetical questions satisfies Rule 701's requirements.

cannot determine whether Dr. Butner's responses to hypothetical questions are based on this same assumption. *Cf. Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 997 (C.D. Cal. 2001) (concluding that if a physician's testimony is equivocal or uncertain, the Court should allow a jury to assess such testimony). Moreover, Dr. Butner expressed reluctance to offer an answer to these hypothetical questions, characterizing his responses as "look[ing] back with the grace of a . . . retrospectroscope." (*Id.* at 121.) In light of this testimony, the Court finds that Dr. Butner's "testimony regarding what he . . . would have done in 20/20-hindsight . . . . may well hinge on credibility, which is for the jury [to] decide." *See In re Prempro Prods. Liab. Litig.*, No. 03-1507, 2006 WL 1981902, at *3 (E.D. Ark. July 13, 2006); *see also Williams v. Lederle Labs.*, 591 F. Supp. 381, 387 (S.D. Ohio 1984); *cf. In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, MDL No. 05-1708, 2007 WL 2023569, at *5 (D. Minn. July 6, 2007).

Second, the hypothetical questions posed to Dr. Butner are ambiguous for an additional reason: they do not draw a clear distinction between Levaquin's tendon toxicity as compared with other fluoroquinolones, and Levaquin's tendon toxicity as compared with non-fluoroquinolones. Dr. Butner testified that he was not aware of the distinctions in tendon toxicity among the fluoroquinolones. (Butner Dep. at 117-18.) Therefore, when Karkoska's counsel asked Dr. Butner whether his "opinion as far as what [he] would have prescribed" would have changed "[i]f Levaquin at the time had been reported to be 10 times more tendon toxic **than a non-Fluoroquinolone**," (*id.* at 111 (emphasis added)), Karkoska's counsel did not inquire as to the relevance of distinctions in tendon toxicity among the fluoroquinolones. Later in the deposition,

however, both Dr. Butner and Karkoska's counsel appear to muddle the inquiry. When Karkoska's counsel asked Dr. Butner whether the distinction among fluoroquinolones "would have been important in [Dr. Butner's] prescribing practice to know that Levaquin was found to be more tendon toxic than Cipro," Dr. Butner referenced the previous question about Levaquin's tendon toxicity compared with non-fluoroquinolones:

> As you, I guess, are attempting to lead me to previously with your questions when you described 10, 20, whatever number of more times more toxic, of course, when I look at any medication, I look at its relative risk. . . . Then I play off against that how much effectiveness do I get for the alleviation of a symptom or disease and what is my best estimate given all the different factors, as I am aware of them, with regards to each individual patient, where can I get the best and biggest and safest and cheapest bang for the buck, again, emphasizing safety and all the other things that I just mentioned. So, sure, if something had become aware—if I had become aware of a circumstance where this medicine, this Levaquin, or some other medicine was having huge issues, I would consider it.

(*Id.* at 117-18.) Because the Court cannot determine from this testimony whether Dr. Butner is comparing the risk of Levaquin as compared with other fluoroquinolones such as Ciprofloxacin, or whether he is comparing the risk of Levaquin as compared with non-fluoroquinolones, the Court cannot determine as a matter of law that defendants' inadequate warning was not a substantial factor in bringing about Karkoska's injury. *See Nguyen v. Nguyen*, 565 N.W.2d 721, 724 (Minn. Ct. App. 1997).

III. COUNTS III THROUGH VIII

Defendants also move for summary judgment on Counts III through VIII, arguing that those causes of action fail in the absence of proximate causation. In response, Karkoska's counsel filed an affidavit pursuant to Rule 56(f) of the Federal Rules of Civil

Procedure, stating that "[d]iscovery on these [claims], particularly sales and marketing documents and depositions, is not far along." (Goldser Aff. at 2, Docket No. 1305.) The affidavit further explains that "[s]ales and marketing documents are still being produced" and that the parties have scheduled depositions "of key sales and marketing witnesses." (*Id.*)

Federal Rule of Civil Procedure 56(f) permits a Court to deny a motion for summary judgment "[i]f a party opposing the motion shows by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition." Fed. R. Civ. P. 56(f). Thus, Rule 56(f) "allows a summary judgment motion to be denied . . . if the nonmoving party has not had an opportunity to make full discovery." *Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986).

The Court finds that the Rule 56(f) affidavit presents specific reasons for Karkoska's inability to present facts essential to his opposition to the motion for summary judgment on these counts. The Rule 56(f) affidavit also suggests that discovery will enable Karkoska to show that there are genuine issues of material fact as to these claims. *See Duffy v. Wolle*, 123 F.3d 1026, 1040 (8th Cir. 1997). The Court therefore denies summary judgment as to Counts III through VIII without prejudice.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that defendants' Motion for Summary Judgment as to Plaintiff Edward Karkoska [08-MDL-1943, Docket No. 726; 07-CV-3960, Docket No. 47] is

DENIED. Plaintiff Edward Karkoska's Motion to Strike [08-MDL-1943, Docket No. 1433] is **DENIED as moot**.

DATED: July 26, 2010
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge